AND
RIEFS

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Nos. 15-1039 and 15-1195

IN THE

Supreme Court of the United States

SANDOZ INC.,

Petitioner,

v.

AMGEN INC., ET AL.,

Respondents.

ON WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF OF *AMICUS CURIAE* GENENTECH, INC. IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICUS CURIAE*

Genentech is one of the world's leading biotechnology companies. As such, it develops treatments for unmet medical needs, especially in the areas of oncology, immunology, neuroscience, metabolism, and infectious disease. Its products include some of the most groundbreaking treatments for cancer, heart attack and stroke, macular degeneration, and other serious or life-threatening medical conditions. To accomplish its critical public-health goals, Genentech invests heavily in research and development. Its approximately 1,200 researchers and scientists and 125 postdocs work in state-of-the-art facilities to push the boundaries of medical knowledge—including by developing biological drugs, or "biologics." Given this commitment to developing innovative treatments using biologics, Genentech has a significant interest in ensuring a proper interpretation of the Biologics Price Competition and Innovation Act of 2009 (the Biologics Act).[1]

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[1] The parties have consented to the filing of this *amicus* brief. No counsel for a party authored the brief in whole or in part. No party, counsel for a party, or any person other than *amicus* and its counsel made a monetary contribution intended to fund the preparation or submission of the brief.

INTRODUCTION AND SUMMARY OF ARGUMENT

The Biologics Act is a litigation-focused statute. Like the Patent Act (which has governed litigation involving patentees for more than a century), and the Hatch-Waxman Act (which governs litigation over generic drugs), the Biologics Act regulates litigation over patent rights. As Sandoz itself recognizes, among the Act's goals is to "facilitat[e] early resolution of potential patent disputes" between biologic pioneers and subsequent producers of biosimilar products. Sandoz Br. 10. It does so by requiring that pioneers and biosimilar applicants exchange certain information, and by specifying the process for litigation that may (and ordinarily will) follow. *See id.* at 10-12.

Despite the fact that private litigation is at the heart of the Biologics Act, Sandoz contends that enforcing the 180-day notice provision contained in 42 U.S.C. § 262(*l*)(8)(A) amounts to impermissibly implying a private right of action. Sandoz Br. 28-29, 43-56 (citing, among other cases, *Alexander v. Sandoval*, 532 U.S. 275 (2001)).

That argument misunderstands this Court's jurisprudence concerning private rights of action. The implied-right-of-action cases on which Sandoz relies concern statutes in which enforcement occurs through mechanisms other than private lawsuits, such as actions by the government. Here, by contrast, Congress has enacted pages and pages of statutory text directed at structuring litigation between private parties. Sandoz's contrary argument distorts the

implied-right-of-action cases beyond recognition by reducing Congress's express notice requirement to a nullity. And it ignores the established principle that Congress does not implicitly abrogate the federal courts' inherent authority to award all appropriate relief for violations of federal law. Sandoz ends up proposing a statutory interpretation that is a recipe for chaos, requiring billion-dollar questions involving lifesaving drugs to be litigated in a hasty fashion. Neither the Biologics Act nor this Court's cases support that result.

1. The best way to understand the Biologics Act is to begin with what it does *not* do. The Act does not keep anyone out of the market for biologics. It does not prevent any company from undertaking the ordinary process—which every biologics pioneer goes through—of proving the safety and efficacy of its drugs to the FDA. If a company does so successfully, it can begin selling its products straightaway.

In addition, the Biologics Act provides a second route to market entry—a shortcut that offers streamlined FDA approvals. Specifically, a company may file an abbreviated licensing application, which allows it to piggyback on the earlier efforts of a biologic pioneer. The applicant need only show that its product is biosimilar to the pioneer biologic.

This shortcut is immensely valuable for biosimilar applicants, because it saves them the time and expense of a full FDA inquiry into safety and efficacy. But Congress understood that shortcuts can lead to wrong turns, so it made sure to include safeguards. It imposed a series of detailed

requirements on both the applicants seeking to take the shortcut and on the pioneers who initially proved the safety and efficacy of their biologics to the FDA. The reasons for these requirements are simple and salutary: to promote competition while fostering innovation; and to avoid the litigation free-for-all that otherwise would result.

Among the Act's key provisions is a mandatory notice requirement. After the FDA licenses a biosimilar product to an applicant seeking to use the statutory shortcut, the applicant must notify the biologic pioneer at least 180 days before it goes to market. This notice period gives the pioneer time to seek a preliminary injunction based on any patents that are not already the subject of litigation, pursuant to the multi-step process set forth in 42 U.S.C. § 262(*l*). *See* Pet. App. 6a-7a; *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1055-58 (Fed. Cir. 2016). And, if the pioneer does seek injunctive relief, the notice provision (and corresponding limitation on marketing the biosimilar drug) enables the reviewing court to assess the patent-law questions with appropriate deliberation—rather than being forced into a snap judgment with months' (and hundreds of millions of dollars') worth of the biosimilar product already on trucks, ready to roll. As Judge Taranto recently explained, this framework reflects Congress's "aim to avoid the uncertainties and deficiencies associated with a process in which requests for temporary restraining orders and preliminary injunctions are presented and adjudicated on short notice." *Apotex*, 827 F.3d at 1063.

2. Sandoz wants to take the statutory shortcut without paying the toll. It seeks to reap the benefits of the abbreviated licensing procedure while disregarding the accompanying requirements. The Court should prevent Sandoz—and the scores of biosimilar applicants who would mimic its approach—from ignoring Congress's explicit instructions. As Amgen explains, the Biologics Act makes clear that notice of commercial marketing must *follow* the FDA's issuance of a license. Amgen Br. 27-42. That argument about the clear text and structure of the Act need not be rehashed here. The same is true of Amgen's further explanation of how the Act requires—again through the use of clear, mandatory language—that a biosimilar applicant furnish its application and manufacturing information to the biologic pioneer. *Id.* at 58-67.

3. Rather than repeating those arguments, Genentech submits this brief to address Sandoz's claim that to enforce the Biologics Act's notice requirement is to imply a private right of action where none exists. *See* Sandoz Br. 43-44; *see also* U.S. Br. 35.

On the contrary, the Act—like the broader system of patent enforcement to which it belongs—revolves around disputes litigated between private parties. It is predicated upon the ability of biologic pioneers to protect their own rights. Sandoz acknowledges as much with its repeated references to private suits for patent infringement. *E.g.*, Sandoz Br. 5 ("[A]ll routes lead to only one place: patent litigation."). There is no need to "imply" or "create" rights of action. They are already there.

Sandoz's argument also is unmoored from the considerations and concerns that animate the Court's implied-right-of-action cases. Its brief relies on cases in which private lawsuits were excluded because Congress had created other mechanisms for enforcing its statutes. Here, however, Sandoz points to no other way to enforce the Biologics Act. This is not a situation in which Congress created a statutory scheme for an administrative agency to enforce. *See, e.g., Alexander*, 532 U.S. at 289. Nor is there any suggestion that criminal penalties attach to noncompliance. *See, e.g., Stoneridge Inv. Partners, LLC. v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 166 (2008). Accordingly, Sandoz is not simply arguing against *private* enforcement of the Act's notice requirement. It is arguing against *any* enforcement.

4. As a fallback, Sandoz contends that even if there is a private right to enforce the Act's notice requirement, courts are powerless to award equitable relief for violations. Sandoz Br. 43-45. But Sandoz's argument has matters backwards. Once it is established that a private right of action exists, the presumption is that judges may award any appropriate relief, including equitable relief. *See, e.g., Franklin v. Gwinnett Cty. Pub. Sch.*, 503 U.S. 60, 69 (1992). Only a clear indication from Congress can support the withdrawal of equitable powers from the federal courts. Sandoz points to no such indication at all.

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For Sandoz to be right, it has to show that (a) Congress inserted an explicit and unqualified

notice requirement in the Biologics Act but did not intend for any entity, public or private, to enforce it; (b) at the same time, Congress meant to sweep away the federal courts' inherent equitable powers to enforce the notice provision, despite not having said a word to that effect; and (c) despite the Act's obvious attempt to bring order and deliberation to litigation over biologics, Congress was actually content to force courts to make snap judgments about complex patent-infringement claims at the very moment biosimilar applicants stand ready to (or have already begun to) enter the market. It would be strange for Congress to have gone to the trouble of developing a careful statutory regime that was so easily circumvented. And, in fact, Congress did no such thing. The Biologics Act creates a system for ensuring that biosimilar drugs are brought onto the market in an orderly fashion. This Court should interpret the Act according to its plain text and evident purpose—both of which entail private enforcement of the notice requirement.

ARGUMENT

I. This Court's Cases Support A Private Right Of Action For Violations Of The Notice Requirement.

A. If private parties cannot enforce the notice requirement, no one can.

There's no dispute that the Biologics Act contains a notice provision. The only questions are when it must be satisfied and how it may be enforced. According to Sandoz, there is no private right of action that enables a pioneer—or, as we will see, anybody

else—to enforce Congress's clear directive. *See* Sandoz Br. 43-44; *see also* U.S. Br. 20-22. This argument relies upon the Court's cases concerning implied rights of action, and it fails under any reasonable understanding of those cases.

Before explaining why this is so, it's important to recognize that a threshold argument raised by Amgen pretermits any inquiry into implied rights of action in this case. As Amgen explains, even if the Biologics Act didn't itself allow for private enforcement, that would be no basis for ruling against Amgen here. Amgen Br. 42-43. That is because Amgen has asserted causes of action that unquestionably are available to a private litigant, including state-law claims for unfair competition and unlawful business practices. *See id.*; Pet. App. 9a. Unless those claims are preempted—and Sandoz hasn't argued (and indeed has waived any argument) that they are, *see* Amgen Br. 43—Sandoz's argument against implied rights of action gets it nowhere. *Cf. Apotex*, 827 F.3d at 1063 ("Apotex has not asserted that (8)(A) creates no privately enforceable right, even when asserted as part of an infringement action ....").

In addition, Sandoz's argument about implied rights of action fails even on its own terms.

1. As Sandoz's own brief makes clear, the Biologics Act bears no resemblance to any statute, or any situation, addressed by the Court's decisions on implied rights of action. While the Court has indeed cautioned against conjuring up private lawsuits that Congress did not authorize—as when a government agency or prosecutor is exclusively authorized to

enforce a federal statute—Sandoz seeks a dramatic extension of the doctrine. It asks the Court to displace private suits in a domain where private litigation is the familiar norm; where the statute explicitly contemplates extensive litigation between private parties; and despite the fact that private actions are the only way to enforce the federal law in question.

To understand the dramatic extension that Sandoz requests, it is helpful to review the trajectory of this Court's jurisprudence. During the middle of the twentieth century, the Court sometimes would imply the existence of a private right of action in a statute, in order to effectuate the statute's perceived goals, without conducting a detailed inquiry into Congress's views about the appropriate mechanism for enforcement. The "high water mark of judicially inferred remedies" may have been *J.I. Case Co. v. Borak*, 377 U.S. 426 (1964). *See* Richard H. Fallon, Jr. et al., *Hart & Wechsler's The Federal Courts and the Federal System* 739 (7th ed. 2015). There, the Court reasoned that courts must be "alert to provide such remedies as are necessary to make effective the congressional purpose" in enacting a statute. *Borak*, 377 U.S. at 433.

Whether *Borak* was merely an anomaly,[2] or

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[2] *See Cannon v. Univ. of Chicago*, 441 U.S. 677, 736 (1979) (Powell, J., dissenting) ("*Borak*, rather than signaling the start of a trend in this Court, constitutes a singular and ... aberrant interpretation of a federal regulatory statute.").

emblematic of a broader trend,[3] by the 1970s the Court had shifted its focus to more evident indications of congressional intent. *See Alexander*, 532 U.S. at 287 (noting that in *Cort v. Ash*, 422 U.S. 66 (1975), the Court "abandoned" the old "understanding" exemplified by *Borak*, "and ha[s] not returned to it since"). Thus, the Court has explained, the judicial role is to implement legislative choices about the proper means of enforcement. *See, e.g., Gonzaga Univ. v. Doe*, 536 U.S. 273, 285 (2002) (explaining that the relevant question is "whether or not Congress intended to confer individual rights upon a class of beneficiaries").

The Court accordingly "swor[e] off the habit of venturing beyond Congress's intent," instead treating the discernment of enforcement mechanisms as a question of statutory interpretation like any other. *Alexander*, 532 U.S. at 287. The key question is not how best to effectuate Congress's goals; it is how Congress itself intended enforcement to occur. *See, e.g., Transamerica Mortg. Advisors, Inc. v. Lewis*, 444 U.S. 11, 15-16 (1979) ("[W]hat must ultimately be determined is whether Congress intended to create the private remedy asserted ...."). So in interpreting a statute's remedial scheme, the starting points for analysis are the same ones a court uses in interpreting the substantive rights protected by the statute: "text and structure." *Alexander*, 532 U.S. at 288.

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[3] *See Alexander*, 532 U.S. at 287 (describing *Borak* as emblematic of "the understanding of private causes of action that held sway" in the 1960s).

This approach is rooted in the separation of powers. The Court has taught that it is for "Congress rather than the courts" to "control[] the availability of remedies for violations of statutes." *Wilder v. Virginia Hosp. Ass'n*, 496 U.S. 498, 508 n.9 (1990). Just as judges must respect legislative decisions about the substance of federal law, they must likewise respect legislative decisions about how rights are to be enforced. *See Alexander*, 532 U.S. at 286 ("Like substantive federal law itself, private rights of action to enforce federal law must be created by Congress.").

2. These principles are particularly important when Congress has created mechanisms other than private lawsuits for enforcing the rights it created.

For instance, in one of Sandoz's primary cases, *Alexander v. Sandoval*, the Court rejected the suitability of private enforcement when the relevant statute was "'phrased as a directive *to federal agencies* engaged in the distribution of public funds.'" 532 U.S. at 289 (emphasis added) (quoting *Univs. Research Ass'n, Inc. v. Coutu*, 450 U.S. 754, 772 (1981)). After all, when Congress has given enforcement responsibility to an agency, "'[t]here [is] far less reason to infer a private remedy in favor of individual persons.'" *Id.* (quoting *Cannon*, 441 U.S. at 690-91).

Those same considerations applied in *Gonzaga*, upon which Sandoz also relies. Sandoz Br. 43-44. There, the Court declined to find a private right of action to enforce the Family Educational Rights and Privacy Act. *Gonzaga*, 536 U.S. at 276. In so doing, it again relied on an agency's enforcement authority: "Congress expressly authorized the Secretary of

Education to 'deal with violations' of the Act ... and required the Secretary to 'establish or designate [a] review board' for investigating and adjudicating such violations." *Id.* at 289 (emphasis omitted, second alteration in original) (quoting 20 U.S.C. § 1232g); *see also id.* at 290 (distinguishing cases in which "an aggrieved individual lacked any federal review mechanism").

So too in *Stoneridge*, cited in U.S. Br. 21, and *Touche Ross & Co. v. Redington*, 442 U.S. 560 (1979), cited in Sandoz Br. 51, 53, and U.S. Br. 20-21. Both cases declined to find private rights of action, and both relied on the fact that the underlying statutes were meant to be enforced by prosecutors or by financial regulators. In *Stoneridge*, the Court noted the availability of "criminal penalties ... and civil enforcement by the SEC" to enforce legal rights. 552 U.S. at 166. That federal authority was ample to enforce the statute; the SEC's "enforcement power is not toothless," and "criminal penalties are a strong deterrent." *Id.* And in *Touche Ross*, the Court implied no private right of action because it found that "[t]he information contained in the [reports required by the statute] is intended to provide the [SEC], the [New York Stock] Exchange, and other authorities with a sufficiently early warning to enable *them* to take appropriate action to protect investors." 442 U.S. at 570 (emphasis added).[4]

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[4] *See also, e.g., Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 117 (2011) (finding no private right of action where "Congress vested authority to oversee compliance with the" relevant law in the Department of Health and Human Services "and assigned no auxiliary enforcement role to covered entities"); *Horne*

This same principle explains the Federal Circuit decisions that Mylan relies upon in its amicus brief supporting Sandoz. *See* Mylan Br. 13-14. In those cases, the Federal Circuit held that certain procedural requirements of the Hatch-Waxman Act did not create a private right of action that could be enforced in private litigation.[5] But the result in those cases was driven by the fact that the Hatch-Waxman Act not only provides for government enforcement of its provisions—it requires it. The Federal Food, Drug, and Cosmetic Act, of which the Hatch-Waxman Act is a part, mandates that all "proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). Indeed, that mandate is so clear that the parties in *Mylan Pharms., Inc. v. Thompson* had

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v. Flores, 557 U.S. 433, 456 n.6 (2009) (finding that the No Child Left Behind Act "is enforceable only by the agency charged with administering it" rather than by private parties); *Karahalios v. Nat'l Fed'n of Fed. Emps., Local 1263*, 489 U.S. 527, 529 (1989) (finding no private right of action "[b]ecause we decide that Congress vested exclusive authority over [the relevant statutory] duty in the Federal Labor Relations Authority ... and its General Counsel").

[5] *See Minn. Mining & Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775, 783 (Fed. Cir. 2002) (holding no right to challenge generic company's paragraph IV certification in infringement litigation); *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1376 (Fed. Cir. 2002) (holding district court in infringement action could not sanction allegedly improper conduct before FDA); *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1329-30 (Fed. Cir. 2001) (holding no private enforcement of statutory limitations on which patents may be listed in "Orange Book"), *superseded by statute*, 21 U.S.C. § 355(j)(5)(C)(ii)(I), *as recognized in Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 408-09 (2012).

to agree that a private action was barred. 268 F.3d 1323, 1330 (Fed. Cir. 2001).[6]

3. These cases exemplify situations in which Congress has charged a governmental authority with enforcing a statute. And in those circumstances, there is little reason to imply an additional right for private individuals absent some indication in the statute. At the same time, the cases leave undisturbed the commonsense proposition that it would be exceedingly odd for Congress to go to the trouble of enacting a statute unless *someone* was empowered to enforce it.

That latter situation is the one presented by the Biologics Act. Sandoz does not suggest that there is anyone other than private actors who is empowered to enforce the notice requirement. *Cf. Apotex*, 827 F.3d at 1064 (noting in a related case that the defendant did not "identif[y] any statutory commitment to a government agency of responsibility or authority to enforce or to seek to enforce the (8)(A) command"). When it comes to enforcing the 180-day notice requirement, the enforcer is a private actor, or

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[6] Notably, Congress subsequently overruled different aspects of this decision, in ways that support the rule we advocate here. Specifically, Congress provided that a generic applicant sued for patent infringement may bring a counterclaim to challenge the allegedly improper inclusion of a patent in the Orange Book. 21 U.S.C. § 355(j)(5)(C)(ii)(I); *see Caraco*, 566 U.S. at 408-09. In so doing, Congress took care to specify that that defense does not create an independent cause of action. It therefore reinforced that (unlike here) government enforcement remains paramount in the FDCA context, and that Congress knows how to specify government enforcement when it wishes to do so.

it is nobody. The prospect of private actions being displaced by other enforcement mechanisms, which is at the heart of the cases Sandoz cites, is simply absent. Instead, Sandoz finds itself forced to argue that for all its care and specificity, Congress intended that the notice requirement would be unenforceable. Not only is this inference implausible; it finds no support in this Court's right-of-action cases.

B. No right of action need be "implied" in this case, for the Biologics Act revolves around litigation between private parties.

As the previous section illustrated, the contrast between this case and the Court's implied-right decisions couldn't be starker. The Biologics Act is all about private litigation between private parties, and nowhere does it discuss or authorize governmental enforcement.

The notice provision falls within subsection *l* of the Act, titled "Patents," which spells out an intricate and thorough procedure for ensuring the orderly and informed litigation of patent rights. Upon filing for shortcut approval, the biosimilar applicant must disclose information about its application to the biologic pioneer so that the pioneer can assess whether its patent rights are threatened. 42 U.S.C. § 262(*l*)(2). Following this disclosure, the biologic pioneer and the biosimilar applicant exchange lists of patents that may be implicated by the application. *See id.* § 262(*l*)(3)(A), (B)(i). The applicant must then explain its basis for believing that there is no violation of patent rights—for example, because the asserted

patents are invalid, the biosimilar product will not infringe them, or the product will not be marketed until the patent expires. *See id.* § 262(*l*)(3)(B)(ii). The parties ultimately winnow the list of patents down to a set—the so-called "Round One" patents—to be litigated in an "Immediate Patent Infringement Action." *Id.* § 262(*l*)(4)-(6). In short, the statute is structured around private litigation.

The 180-day notice provision is part and parcel of this private-litigation-based regime. It authorizes actions by biologic pioneers to seek "a preliminary injunction prohibiting the [biosimilar applicant] from engaging in the commercial manufacture or sale" of biologics until patent rights that were *not* part of the Round One litigation are resolved. *Id.* § 262(*l*)(8)(B). In addition, Congress specified circumstances under which pioneers may bring declaratory judgments to enforce their rights. *Id.* § 262(*l*)(9). In short, in setting out these procedures, Congress confirmed what everyone already knew: In American law, the enforcement of patents falls to private actors bringing private lawsuits. Those suits are the ubiquitous and well-known mechanism for safeguarding "patent rights whose fair and unhurried adjudication" the notice requirement "is designed to protect." *Apotex*, 827 F.3d at 1063-64.

Sandoz does not dispute that patent-holders are entitled to protect their rights in court. As discussed above, neither does it argue that there is an administrative agency or law-enforcement body charged with enforcing the notice requirement. It argues, in effect, that no one may enforce the notice requirement—which is to say, that the requirement

isn't a requirement at all. Nothing in the Biologics Act's text, structure, or context supports such a reading.

C. An unenforceable notice requirement would have consequences that Congress cannot have intended.

The discussion thus far has explained why concerns about implied rights of action are misplaced in this case, and how private enforcement of the Biologics Act coheres with the Act's plain text as well as the broader system of American patent law. Those points are more than adequate to dispose of Sandoz's arguments for rendering the notice requirement unenforceable. But Sandoz's position also suffers from another flaw: It would yield a regime of litigation whose perverse consequences Congress could not possibly have intended. Sandoz's view of the Act would lead to hurried proceedings involving remarkably high stakes—in short, judges making billion-dollar judgments, sometimes in the course of a day's litigation.

A simple illustration shows why this is so. Imagine a biosimilar applicant who submits a shortcut application to the FDA and begins complying with the Act—for example, by sending the biologic pioneer a copy of its application and a description of its manufacturing process. 42 U.S.C. § 262(*l*)(2)(A). The applicant will appear to the world to be complying with the Act while it seeks FDA approval to market its product. Now imagine that the FDA issues a license, and the applicant immediately begins selling its product—without having given notice to the

pioneer. In short, the applicant decides to ignore the notice requirement Congress expressly set forth in § 262(*l*)(8)(A).

The ending of this story is utterly predictable. The moment the applicant has received FDA approval to market the biosimilar, it will ship as much product as possible, as fast as possible. (More on that in a moment.) And the biologic pioneer, in order to prevent the market from being flooded with a product whose legality hasn't been resolved, will seek expedited proceedings in an effort to restrain those sales. As Judge Taranto explained, without the possibility of a straightforward proceeding that merely considers whether the notice requirement (and accompanying marketing limitation) was violated, a biologic pioneer "will have to race to court for immediate relief to avoid irreparable harm from market entry." *Apotex*, 827 F.3d at 1065. Rather than making a simple motion to enforce the 180-day buffer Congress created, the pioneer will need to argue for "a temporary restraining order or a preliminary injunction" that involves the full panoply of patent issues. *Id.* In short, rather than resolving the motion with a quick glance at the calendar, the district court will need to conduct an intensive assessment of the parties' positions, including the likelihood that the pioneer will ultimately prevail on its claim of patent infringement. This is "precisely the hurried motion practice that [the notice requirement] is designed to replace by ensuring a defined amount of time for pre-launch litigation." *Id.*

Stranger still, Sandoz's position would apply in equal measure to an applicant who gives notice of its

intent to market beginning in 180 days, only to break its word and begin selling its product a day later. Again, the pioneer would need to race to court in the hope of convincing a judge to enter an immediate TRO in a high-stakes case involving complex technologies and complicated claims. *See id.* at 1062 (a biologic pioneer "needs time to make a decision about seeking relief based on yet-to-be litigated patents, and a district court needs time for litigants to prepare their cases, in a complicated area, to provide a reliable basis for judgment").[7]

This is the opposite of how the Biologics Act is supposed to work. The notice requirement, and the accompanying marketing limitation, are designed to bring order and predictability to litigation. It is "evident on the face of § 262(*l*)" and "confirm[ed]" by the "Act's legislative history" that Congress intended to "avoid the uncertainties and deficiencies associated with a process in which requests for temporary restraining orders and preliminary injunctions are

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[7] The same is true under the compromise proposed by the government. The Acting Solicitor General suggests that, when considering whether to issue a preliminary injunction pending the resolution of infringement claims, district courts may take into account an applicant's failure to give notice. U.S. Br. 36. But this is little solace, for district courts would still be put to the task of making snap judgments about the likelihood of success in patent disputes as biosimilars began rushing into the market notwithstanding unresolved claims of infringement. In fact, this proposed compromise may actually make matters worse. In addition to all of the other issues being litigated in expedited fashion, district courts would have to wade through an additional set of issues: whether notice was given, whether any failure to give notice was in bad faith, whether the failure prejudiced the biologic pioneer, and so forth.

presented and adjudicated on short notice." *Apotex*, 827 F.3d at 1063.

These are not fanciful or hypothetical concerns; they have plagued Hatch-Waxman litigation. In that related context, courts are often forced to decide at breakneck speed whether to delay generic drugs' entry into the market. An injunction that turns out to be unwarranted threatens to "thwart[] the statutory purpose of achieving swift competition by generics." *Teva Pharm. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1311 (D.C. Cir. 2010). Yet if the court delays before acting, it effectively gives the generic manufacturer "precisely the relief it seeks, simply in order to allow the court time to decide whether such relief was warranted." *Id.*

This has placed courts in an "awkward bind," to put things mildly. *See AstraZeneca Pharm. LP v. Burwell*, 197 F. Supp. 3d 53, 55-58 (D.D.C. 2016). In *AstraZeneca*, for example, the court and the patent holder reviewed the FDA's approval decision in less than an hour, then went straight into oral argument followed by an oral decision. Transcript of July 19, 2016, Hearing, Dkt. 77, at 7-8, 64, *AstraZeneca*, No. 1:16-cv-1336 (D.D.C. June 30, 2016). This lightning-fast, patched-together procedure was necessary because, as the generic drug producers themselves explained, "months worth of product" was "loaded onto trucks" and "sitting in quarantine at distributors[,] which is all common practice when generics launch their generic products." *Id.* at 54, 56. AstraZeneca, meanwhile, stood to suffer losses "in the neighborhood of $400,000,000" if those generics

entered the market, "and the company would have no avenue of suit to recover that amount." *Id.* at 73.

Likewise, in a dispute involving generic versions of the antipsychotic drug Abilify, a district court held a hearing on the patent holder's motion for a TRO or preliminary injunction "just two hours after" FDA approval. *Otsuka Pharm. Co. v. Burwell*, No. 8:2015-cv-852, 2015 WL 1962240, at *1 (D. Md. Apr. 29, 2015). The very next day, the court churned out a 24-page decision that required it to analyze the FDA's approval of the generics' labeling under the two-step *Chevron* framework. A deliberative process that customarily takes months was crammed into a day. *See also* Amgen Br. 41-42 (providing additional examples).

Congress plainly learned from this experience, which long predates the Biologics Act. It inserted a 180-day notice requirement in the Biologics Act to avoid rapid-fire litigation in situations where mistakes can never fully be fixed. *See Apotex*, 827 F.3d at 1063 (noting the "reliability-reducing rush that would attend requests for relief against immediate market entry that could cause irreparable injury"). The notice period ensures that the parties and the courts can litigate a preliminary injunction in an orderly fashion and with the deliberation it deserves, rather than racing through a TRO proceeding while products are being loaded into trucks.

Contrary to Sandoz's argument (Sandoz Br. 39-42), the purpose of the Act will not be served if notice is given prior to FDA licensing. That is because the

backbone of the Act is a system of litigation under which patent disputes often will not be fully resolved by the time the FDA licenses a biosimilar. The Act does obligate both parties to *identify* all patents that might be infringed by the biosimilar product described in the application. 42 U.S.C. § 262(*l*)(3). But not all such patents will be litigated prior to FDA licensure. Instead, the Act expressly directs the parties to narrow the original list of patents to only a subset that will be litigated in an immediate infringement action (and, indeed, it gives the biosimilar applicant ultimate control over how many patents will be part of that Round One suit).[8] All other patents are saved for a second round of litigation. Round Two can include, for example, patents whose litigation the parties have agreed to defer (for instance, because their relevance will not be clear until after the FDA completes its review); patents that the biologic pioneer wished to litigate earlier, but that the biosimilar applicant excluded through its control over Round One litigation; and patents that were issued to or licensed by the biologic pioneer after the parties exchanged their initial lists of patents, *see id.* § 262(*l*)(7).[9] The requirement of notice after FDA

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[8] *See id.* § 262(*l*)(4)-(6); *Apotex*, 827 F.3d at 1062 (noting that section 262(*l*) "gives the [biosimilar] applicant substantial authority to force … a limitation on the scope" of immediate litigation even of patents that the biologic pioneer "has good grounds to assert"); Sandoz Br. 39 (stating that the process set forth by the Biologics Act is "meant to narrow and allow [the biosimilar applicant] to control the scope of immediate litigation").

[9] Additionally, as Amgen notes, if the government is correct that § 271(e) does not establish an artificial act of infringement with respect to manufacturing process patents, those patents

licensure ensures that litigation over these categories of patents—as well as any patents that the parties have begun to litigate but whose resolution isn't yet determined at the time of licensure—can occur within a 180-day buffer period rather than on the eve of a biosimilar's entry into the market.

If (as Sandoz claims, Sandoz Br. 30-42) notice could come near the beginning of a biosimilar's approval process, the facts would be too contingent and undeveloped to allow meaningful consideration of the suitability and shape of injunctive relief. The parties would be arguing about the terms of a hypothetical injunction of a product that might not be approved for several years—if at all. And even if a license was eventually granted, it might look very different from the one the biosimilar applicant initially sought. Indeed, as Amgen notes, in this very case Sandoz's application was amended 30 times before FDA licensure. *See* Amgen Br. at 24.

Given the many unknowns prior to FDA licensure—including the uncertainty about when, if ever, a biosimilar product may be approved for sale—allowing statutory notice before FDA licensure is little better than requiring no notice at all. Premature notice would do nothing to remove the need for biologic pioneers to race to court after licensure to seek an immediate injunction. Nor would premature notice relieve district courts from making snap

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may not be eligible for inclusion in Round One, because the ambiguity about what (if any) license ultimately will issue may preclude declaratory judgment jurisdiction. *See* Amgen Br. 33-34; U.S. Br. 25.

judgments about the suitability and contours of injunctive relief in complicated cases. Sandoz's position, then, is not just countertextual; it also renders the Biologics Act incapable of solving a central problem Congress set out to address.

It bears repeating that no company is forced to take the shortcut that triggers the Act's notice requirement. If an applicant wants to avoid the disclosure and notice obligations imposed by the Act, it always has the right to prove the safety and efficacy of its drugs itself. But if an applicant elects to take the statutory shortcut by showing that its drug is biosimilar to an approved biologic, and if it receives approval for an FDA license, it must notify the pioneer at least 180 days before it begins selling. If it fails to give sufficient notice, a federal judge can enjoin it from going to market for up to 180 days. There is nothing novel or surprising about such a regime. It is a straightforward application of Congress's commands, which reflect an attempt to create a much-needed solution to the problem of drive-thru litigation of complex patents.

II. Nothing In The Act Overcomes The Presumption That Federal Courts May Award Any Appropriate Relief, Including Injunctive Relief.

Sandoz's position fares no better if it is recast from an argument about private rights of action into a claim that injunctive relief is unavailable to enforce the Biologics Act's notice requirement. *See* Sandoz Br. 44-45. Once the Court finds that biologic pioneers can sue to enforce the Biologics Act, the well-established

presumption is that the federal courts called upon to resolve such suits may order any appropriate relief, including injunctive relief. Any reluctance to recognize private rights of action falls away when it is time to consider forms of relief. That is because "'the question whether a litigant has a 'cause of action' is analytically distinct and prior to the question of what relief, if any, a litigant may be entitled to receive.'" *Franklin*, 503 U.S. at 69 (quoting *Davis v. Passman*, 442 U.S. 228, 239 (1979)).

Accordingly, in cases like this one, where the statutory scheme depends on private enforcement, the controlling authorities are "the long line of cases in which the Court has held that if a right of action exists to enforce a federal right and Congress is silent on the question of remedies, a federal court may order any appropriate relief." *Id.*; *see also Sullivan v. Little Hunting Park, Inc.*, 396 U.S. 229, 239 (1969) ("The existence of a statutory right implies the existence of all necessary and appropriate remedies."); *Porter v. Warner Holding Co.*, 328 U.S. 395, 398 (1946) ("Unless otherwise provided by statute, all the inherent equitable powers of the District Court are available for the proper and complete exercise of [its] jurisdiction.").

Sandoz, then, has it backwards. The drastic restriction of judicial authority that it urges would require a clear congressional mandate. Injunctive relief is available unless Congress has indicated otherwise. *See id.*; *see also Apotex*, 827 F.3d at 1064. And nothing in the Biologics Act suggests that Congress meant to "cabin [a federal court's] usual equitable powers." *United States v. Kwai Fun Wong*,

135 S. Ct. 1625, 1633 (2015). Every indication is that Congress intended for private parties to be able to seek injunctive relief in disputes over biologics. Whereas Sandoz needs to identify some clear basis to deny the federal courts' equitable powers, the Biologics Act points in the opposite direction.

The notice requirement and corresponding marketing limitation of § 262(*l*)(8)(A) are followed immediately (in § 262(*l*)(8)(B)) by a section called "Preliminary injunction." True to its name, that subsection explicitly authorizes injunctive relief. It provides that the pioneer "may seek a preliminary injunction prohibiting the [biosimilar] applicant from engaging in the commercial manufacture or sale of [its] biological product until the court decides the issue of patent validity, enforcement, and infringement" with respect to any Round Two patent. The subsection applies to situations in which the biosimilar applicant has provided notice of its intent to market. So on Sandoz's theory, Congress meant to authorize injunctive relief against an applicant that *did* comply with the notice requirement, but not against an applicant that did *not* comply. The Act provides no support for such an uneven reading, particularly given the presumption that equitable remedies are available unless Congress has indicated otherwise.

The role of the Biologics Act within the broader system of patent litigation further undermines the claim that Congress intended to roll back the equitable powers of the federal courts. Congress has expressly authorized courts to "grant injunctions in accordance with the principles of equity to prevent the

violation of any right secured by patent." 35 U.S.C. § 283. The Biologics Act's notice requirement protects those same rights from being undermined by the launch of an infringing biosimilar before a court has the opportunity to perform any serious analysis of what inevitably are complicated questions of patent law. The Act's careful framework allows a period of deliberation in which pioneers can seek injunctive relief without worrying that an applicant will violate their rights in the meantime. Temporary injunctions against commercial marketing and injunctions against patent infringement thus serve as complementary tools for protecting the same bundle of rights.

In attempting to carry its burden of showing that Congress intended to truncate the federal courts' equitable powers, Sandoz points to § 262(*l*)(9)(B). *See* Sandoz Br. 46. That section applies when a biosimilar applicant initially complies with the Act's requirements but later strays from the statutory path by, for example, failing to give the requisite notice before commercial marketing.[10] In that event, § 262(*l*)(9)(B) allows the biologic pioneer to seek "a declaration of infringement, validity, or enforceability" of certain patents—namely, those patents that the pioneer identified under § 262(*l*)(3)(A) as reasonable prospects for an infringement suit but that have not yet been litigated. According to Sandoz, this provision shows that

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[10] *See* 42 U.S.C. § 262(*l*)(9)(B) (cross-referencing § 262(*l*)(8)(A), which requires notice of commercial marketing, as well as subsections (*l*)(3)(B)(ii), (*l*)(5), (*l*)(6)(C)(i), and (*l*)(7)).

Congress meant to sweep away all other means of enforcing the notice requirement. Sandoz Br. 47.

But § 262(*l*)(9)(B) makes no attempt to address violations of the notice requirement. Allowing the adjudication of patent rights does not cure the harm that is created when the notice requirement is violated—namely, being forced into hasty patent litigation to stave off irreparable harm from market entry. *See supra* 17-20; *Apotex*, 827 F.3d at 1065 (explaining that the prospect of a declaratory judgment is "so gross a mismatch for the (8)(A) right that it cannot fairly be treated, in the absence of any statutory language so stating, as the exclusive remedy for (8)(A)'s violation").

Section 262(*l*)(9) plays a distinctive role within the framework of the Biologics Act. It provides that an applicant who follows the Act's rules enjoys temporary protection from declaratory-judgment suits based on patent rights. 42 U.S.C. § 262(*l*)(9)(A). Conversely, it makes clear that an applicant who breaks those rules is subject to such suits. *See id.* § 262(*l*)(9)(B). But in crafting this framework, Congress did nothing to limit courts' equitable powers to enforce violations of the notice requirement. "Nothing in paragraph (9) declares the exclusivity of the declaratory-judgment actions to which it refers .... There is no language that excludes other remedies for the conduct described." *Apotex*, 827 F.3d at 1064.[11]

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[11] Nor is this a case in which enforcing a statute by injunction would be "judicially unadministrable." *Armstrong v. Exceptional Child Ctr., Inc.*, 135 S. Ct. 1378, 1385 (2015). On the contrary, it is hard to imagine a simpler order than a prohibition

Sandoz also appeals to 35 U.S.C. § 271(e)(4), which it describes as showing "that patent-based remedies 'are the *only remedies* which may be granted by a court' for the artificial acts of infringement created by" the Act. Sandoz Br. 47 (italics added by Sandoz; underlining ours). This section is inapposite, because a violation of the notice provision is not an "artificial act[] of infringement created by" the Act. (By way of contrast, the filing of an abbreviated biosimilar application *is* an artificial act of infringement. *See* 35 U.S.C. § 271(e)(2)(C).) Thus, an injunction against commercial marketing in the absence of notice is not a remedy for artificial infringement, and § 271(e)(4) is facially inapplicable.

If anything, then, § 271(e)(4) underscores the flaws in Sandoz's interpretation. If Sandoz were correct that declaratory-judgment actions are the exclusive remedy for violations of the Act, that reading would have the effect of also foreclosing the "monetary and injunctive infringement remedies expressly authorized by 35 U.S.C. § 271(e)(4) for what is, after all, an infringement under § 272(e)(2)." *Apotex*, 827 F.3d at 1064. If Congress meant to foreclose patent damages, surely it would've said so. This is the very sort of elephants-in-mouseholes reasoning that Sandoz elsewhere decries. *See* Sandoz

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against commercial marketing until 180 days after notice is given. The Biologics Act itself furnishes all the language a court would need to craft its relief. *See* § 262(*l*)(8)(B) (discussing a preliminary injunction that prohibits an applicant "from engaging in the commercial manufacture or sale of" the biologic at issue).

Br. 33 (citing *Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 468 (2001)).

Sandoz comes no closer to carrying its burden of showing that Congress meant to displace the courts' equitable powers when it invokes § 262(*l*)(1)(H). That provision states that if a biologic pioneer discloses certain confidential information that it received from a biosimilar applicant, such disclosure will be "deemed to cause ... irreparable harm for which there is no adequate legal remedy." Sandoz says that this provision forecloses equitable relief to biologic pioneers for applicants' violations of the notice requirement. *See* Sandoz Br. 51-52. But this lone provision about confidentiality does not purport to address the separate questions of when and how biologic pioneers can enforce their *own* rights; it is only concerned with biosimilar applicants and the confidential data they provide. It is implausible to suggest that a provision dealing with breaches of confidentiality was secretly intended to shut the door to injunctive relief for entirely different harms.

Ultimately, Sandoz needs a clear indication from Congress to deny the equitable powers of the federal courts. *See Franklin*, 503 U.S. at 69; *Porter*, 328 U.S. at 398; *cf. United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 496 (2001) ("[W]hen district courts are properly acting as courts of equity, they have discretion unless a statute clearly provides otherwise."); *eBay, Inc. v. MercExchange L.L.C.*, 547 U.S. 388, 391 (2006) ("As this Court has long recognized, 'a major departure from the long tradition of equity practice should not be lightly implied.'" (quoting *Weinberger v. Romero-Barcelo*, 456 U.S. 305,

320 (1982))). The Biologics Act provides no such indication at all.

CONCLUSION

For the foregoing reasons, the Court should hold that injunctive relief is available if a biosimilar applicant does not provide the biologic pioneer with at least 180 days of notice between FDA licensing and commercial marketing, and if an applicant fails to disclose its biologics license application and related information to the pioneer.

Respectfully submitted,

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